

AP35518 (072396.0263) **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Robbins et al.

Customer No.:

21003

Serial No.

10/807,755

Examiner:

Not Yet Assigned

Filed

March 24, 2004

Group Art Unit:

1646

For

EXPRESSION VECTOR **SYNTHETIC** COMPACT COMPRISING DOUBLE-STRANDED DNA MOLECULES

AND METHODS OF USE THEREOF

INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

June 24, 2004

Date

Rochelle K. Seide

32,300

PTO Reg. No

June 24, 2004

Date of Signature

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, Applicants respectfully request that the documents listed below and on the accompanying PTO 1449 be considered by the Examiner and made of record in the above-referenced application. Copies of the listed documents are enclosed.

Martinez et al. Single-Stranded Antisense siRNAs Guide Terget RNA Cleavage 1. in RNAi. Cell 2002;110:563-74;

- Zeng et al. Both Natural and Designed Micro RNAs Can Inhibit the Expression of Cognate mRNAs When Expressed in Human Cells. Mol. Cell 2002;9:1327-1333;
- 3. Stanojevic and Young. A Highly Potent Artificial Transcription Factor. Biochemistry 2002;41:7209-7216;
- 4. Xia et al. siRNA-mediated gene silencing in vitro and in vivo. Nature Biotech. 2002;20:1006-10;
- Matheos *et al.* Ku antigen, an origin-specific binding protein that associates with replication proteins, is required for mammalian DNA replication. Biochim. Biophys. Acta. 2002;1578:59-72;
- 6. Jacque *et al.* Modulation of HIV-1 replication by RNA interference. Nature 2002;418:435-438;
- 7. Opalinska and Gewirtz. Nucleic-acid therapeutics: basic principles and recent applications. Nat Rev Drug Discov 2002;1:503-14;
- 8. Gary Ruvkun. Glimpses of a Tiny RNA World. Science 2001;2294:797-799;
- 9. Robert Barstead. Genome-wide RNAi. Curr. Opin. Chem. Biol. 2001;5:63-66;
- 10. Phillip D. Zamore. RNA interference: listening to the sound of silence. Nat. Struct. Biol. 2001;8:746-750;
- 11. Fjose *et al.* RNA interference: mechanisms and applications. Biotechnol. Annu. Rev. 2001;7:31-57;
- Zhao et al. Double-Stranded RNA Injection Produces Nonspecific Defects in Zebrafish. Dev. Biol. 2001;229:215-223;
- 13. Kassavetis *et al.* The RNA polymerase III transcription initiation factor TFIIIB participates in two steps of promoter opening. EMBO J. 2001;20:2823-2834;

2

- 14. Mark Lewandoski. Conditional control of gene expression in the mouse. Nat. Rev. Genet. 2001;2:743-755;
- 15. Reinhart *et al.* The 21-nucleotide let-7 RNA regulates developmental timing in Caenorhabditis elegans. Nature 2000;403:901-906;
- 16. Tavernarakis et al. Heritable and inducible genetic interference by double-stranded RNA encoded by transgenes. Nat. Genet. 2000;24:180-183;
- 17. Nakano *et al.* RNA Interference for the Organizer-Specific Gene Xlim-1 in Xenopus Embryos. Biochem. Biophys. Res. Commun. 2000;274:434-439;
- 18. Svoboda *et al*, Selective reduction of dormant maternal mRNAs in mouse oocytes by RNA interference. Development 2000;127:4147-4156;
- 19. Ohkawa and Taira. Control of the Functional Activity of an Antisense RNA by a Tetracycline-Responsive Derivative of the Human U6 snRNA Promoter. Human Gene Ther. 2000;11:577-585;
- 20. Olejnik *et al.* Photocleavable aminotag phosphoramidites for 5'-termini DNA/RNA labeling. Nucl. Acids Res. 1998;26:3572-3576;
- 21. Wang *et al.* Plasmids for the in vitro analysis of RNA polymerase II-dependent transcription based on a G-free template. Biochimica et Biophysica Acta 1998;1397:141-145;
- 22. Tichelaar *et al.* In Vivo Expression of a Variant Human U6 RNA from a Unique, Internal Promoter. Biochemistry 1998;37:12943-12951;
- 23. Nyanguile *et al.* A nonnatural transcriptional coactivator. Proc. Natl. Acad. Sci. USA 1997;94:13402-13406;

- 24. Jacobs and Langland. When Two Strands Are Better Than One: The Mediators and Modulators of the Cellular Responses to Double-Stranded RNA. Virology 1996;219:339-349;
- 25. Berns and Giraud Adenovirus and Adeno-Associated Virus as Vectors for Gene Therapy. Ann. N.Y. Acad. Sci. 1995;772:95-104;
- 26. Alan E. Smith. Viral vectors in gene therapy. Ann. Rev. Microbiol. 1995;49:807-838;
- 27. Yang et al. Cellular and Humoral Immune Responses to Viral Antigens Create Barriers to Lung-Directed Gene Therapy with Recombinant Adenoviruses. J. Virol. 1995;69:2004-2015;
- 28. Izban et al. RNA Polymerase II Ternary Complexes May Become Arrested after Transcribing to within 10 Bases of the End of Linear Templates. J. Biol. Chem. 1995;270:2290-2297;
- Krebs et al. The JC Virus Minimal Core Promoter Is Glial Cell Specific In Vivo.
 J. Virol. 1995;69:2434-2442;
- 30. Pan and Greenblatt. Initiation of Transcription by RNA Polymerase II Is Limited by Melting of the Promoter DNA in the Region Immediately Upstream of the Initiation Site. J. Biol. Chem. 1994;269:30101-30104;
- 31. Lee *et al*. The C. elegans Heterochronic Gene lin-4 Encodes Small RNAs with Antisense Complementarity to lin-14. Cell 1993;75:843-54;
- 32. Richard C. Mulligan. The Basic Science of Gene Therapy. Science 1993;260:926-932;

NY02:482263.1 4

- 33. Hubbell *et al.* Cyclic AMP mediates the direct antiproliferative action of mismatched double-stranded RNA. Proc. Natl. Acad. Sci. USA 1991;88:906-910;
- 34. Zaug *et al.* The Tetrahymena ribozyme acts like an RNA restriction endonuclease.

 Nature 1986;324:429-33;
- 35. Gelboin *et al.* Polyinosinic-Polycytidylic Acid Inhibits Chemically Induced Tumorigenesis in Mouse Skin. Science 1970;167:205-207;
- 36. Levy et al. Inhibition of tumor growth by polyinosinic-polycytidylic acid. Proc.Nat. Acad. Sci. USA 1969;62:357-361; and
- 37. Zeleznick *et al.* Treatment of Leukemic (L-1210) Mice with Double-Stranded Polyribonucleotides (33503). Proc. Soc. Exp. Biol. Med. 1969;130:126-128.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute "prior art." If the Examiner applies the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

This Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits of referenced application. Therefore, Applicants do not believe that any fee is due in connection with the submission of this paper. However, if any fee is due, or if any overpayment has been made, the Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit Account No. 02-4377.

Duplicate copies of this sheet are enclosed.

Respectfully submitted,

BAKER BOTTS LLP

Rochelle K. Seide Patent Office Reg. No. 32,300

Carmella L. Stephens Patent Office Reg. No. 41,328

Attorneys for Applicants

30 Rockefeller Plaza 44th Floor New York, NY 10112-4498

(212) 408-2626

to charge any such fee or credit any overpayment, to our Deposit Account No. 02-4377.

Duplicate copies of this sheet are enclosed.

Respectfully submitted,

BAKER BOTTS LLP

Rochelle K. Seide

Patent Office Reg. No. 32,300

Carmella L. Stephens

Patent Office Reg. No. 41,328

Attorneys for Applicants

30 Rockefeller Plaza

44th Floor

New York, NY 10112-4498

(212) 408-2626

Page 1 of 3 JUN 2 8 2004 Form-PTO-1449 S.S. Department of Commerce REV. 2-82) Patent and Trademark Office Atty. Docket No. Serial No. AP35518 (072396.0263) 10/807,755 MADEMARK Applicants INFORMATION DISCLOSURE STATEMENT Robbins et al. Filing Date Group Art Unit BY APPLICANT March 24, 2004 1646 (Use several sheets if necessary) **U.S. PATENT DOCUMENTS** Subclass Filing Date Document No. Date Class *Exam. Name ifAppropriate Init. FOREIGN PATENT DOCUMENT Translator SubClass Class Yes Document No. OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.) Martinez et al. Single-Stranded Antisense siRNAs Guide Terget RNA Cleavage in RNAi. Cell 2002;110:563-74. 2. Zeng et al. Both Natural and Designed Micro RNAs Can Inhibit the Expression of Cognate mRNAs When Expressed in Human Cells. Mol. Cell 2002;9:1327-1333. 3. Stanojevic and Young. A Highly Potent Artificial Transcription Factor. **Biochemistry** 2002;41:7209-7216. Xia et al. siRNA-mediated gene silencing in vitro and in vivo. Nature Biotech. 2002;20:1006-Matheos et al. Ku antigen, an origin-specific binding protein that associates with replication proteins, is required for mammalian DNA replication. Biochim. Biophys. Acta. 2002;1578:59-Jacque et al. Modulation of HIV-1 replication by RNA interference. Nature 2002;418:435-438. 6. Opalinska and Gewirtz. Nucleic-acid therapeutics: basic principles and recent applications. Nat 7. Rev Drug Discov 2002;1:503-14. Gary Ruvkun. Glimpses of a Tiny RNA World. Science 2001;2294:797-799. 8. Robert Barstead. Genome-wide RNAi. Curr. Opin. Chem. Biol. 2001;5:63-66. 10. Phillip D. Zamore. RNA interference: listening to the sound of silence. Nat. Struct. Biol. 2001:8:746-750. Examiner Date Considered

^{*} Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office		Atty. Docket No. AP35518 (072396.0263)	Serial No. 10/807,755	
ي ا	DISCLOSURE STATEMENT	Applicants Robbins et al.		
BY APPLICANT (Use several sheets if necessary)		Filing Date March 24, 2004	Group Art Unit 1646	
	se et al. RNA interference: me 1;7:31-57.	chanisms and applications.	Biotechnol. Annu. Rev.	
Bio	no et al. Double-Stranded RNA Inj 1. 2001;229:215-223.			
13. Kas	Kassavetis et al. The RNA polymerase III transcription initiation factor TFIIIB participates in two steps of promoter opening. EMBO J. 2001;20:2823-2834.			
200	Mark Lewandoski. Conditional control of gene expression in the mouse. Nat. Rev. Genet. 2001;2:743-755.			
ele	Reinhart <i>et al.</i> The 21-nucleotide let-7 RNA regulates developmental timing in Caenorhabditis elegans. Nature 2000;403:901-906.			
· end	Tavernarakis et al. Heritable and inducible genetic interference by double-stranded RNA encoded by transgenes. Nat. Genet. 2000;24:180-183.			
Bio	Nakano <i>et al.</i> RNA Interference for the Organizer-Specific Gene Xlim-1 in Xenopus Embryos. Biochem. Biophys. Res. Commun. 2000;274:434-439.			
int	Svoboda <i>et al</i> , Selective reduction of dormant maternal mRNAs in mouse oocytes by RNA interference. Development 2000;127:4147-4156.			
Re	Ohkawa and Taira. Control of the Functional Activity of an Antisense RNA by a Tetracycline-Responsive Derivative of the Human U6 snRNA Promoter. Human Gene Ther. 2000;11:577-585.			
20. Ol	Olejnik et al. Photocleavable aminotag phosphoramidites for 5'-termini DNA/RNA labeling.			
21. W	Wang et al. Plasmids for the in vitro analysis of RNA polymerase II-dependent transcription based on a G-free template. Biochimica et Biophysica Acta 1998;1397:141-145.			
	Tichelaar et al. In Vivo Expression of a Variant Human U6 RNA from a Unique, Internal Promoter. Biochemistry 1998;37:12943-12951.			
23. Ny	Nyanguile et al. A nonnatural transcriptional coactivator. Proc. Natl. Acad. Sci. USA			
24. Ja of	cobs and Langland. When Two Strands Are Better Than One: The Mediators and Modulators the Cellular Responses to Double-Stranded RNA. Virology 1996;219:339-349.			
	erns and Giraud Adenovirus and Adeno	deno-Associated Virus as Vectors for Gene Therapy. Ann.		
Evaminer	Da	te Considered		

Examiner

^{*} Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

			Page 3 of 3		
Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office		Atty. Docket No. AP35518 (072396.0263)	Serial No.		
(,		Applicants	10/807,755		
INFORMATION DISCLOSURE STATEMENT		Robbins et al.			
BY APPLICANT		Filing Date	Group Art Unit		
(Use several sheets if necessary)		March 24, 2004	1646		
26.	Alan E. Smith. Viral vectors in gene th	nerapy. Ann. Rev. Microbiol.	1995;49:807-838.		
. 27.	Yang et al. Cellular and Humoral Immune Responses to Viral Antigens Create Barriers to Lung-Directed Gene Therapy with Recombinant Adenoviruses. J. Virol. 1995;69:2004-2015.				
. 28.					
·	Izban et al. RNA Polymerase II Ternary Complexes May Become Arrested after Transcribing to within 10 Bases of the End of Linear Templates. J. Biol. Chem. 1995;270:2290-2297.				
29.	Krebs et al. The JC Virus Minimal Core Promoter Is Glial Cell Specific In Vivo. J. Virol. 1995;69:2434-2442.				
30.	Pan and Greenblatt. Initiation of Transcription by RNA Polymerase II Is Limited by Melting of the Promoter DNA in the Region Immediately Upstream of the Initiation Site. J. Biol. Chem. 1994;269:30101-30104.				
31.	Lee et al. The C. elegans Heterochronic Gene lin-4 Encodes Small RNAs with Antisense Complementarity to lin-14. Cell 1993;75:843-54.				
. 32.	Richard C. Mulligan. The Basic Science of Gene Therapy. Science 1993;260:926-932.				
. 33.	Hubbell et al. Cyclic AMP mediates the direct antiproliferative action of mismatched double-stranded RNA. Proc. Natl. Acad. Sci. USA 1991;88:906-910.				
34.	Zaug et al. The Tetrahymena ribozyme acts like an RNA restriction endonuclease. Nature 1986;324:429-33.				
35.	Gelboin <i>et al.</i> Polyinosinic-Polycytidylic Acid Inhibits Chemically Induced Tumorigenesis in Mouse Skin. Science 1970;167:205-207.				
36.	Levy et al. Inhibition of tumor growth by polyinosinic-polycytidylic acid. Proc. Nat. Acad. Sci. USA 1969;62:357-361.				
37.	Zeleznick <i>et al.</i> Treatment of Polyribonucleotides (33503), Proc. So	` ,	e with Double-Stranded		

Examiner Date Considered

^{*} Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.